

TRANSMITTAL LETTER TO THE UNITED STATES

DESIGNATED/ELECTED OFFICE (DO/EO/US)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

INTERNATIONAL APPLICATION NO.

PCT/EP04/07882

INTERNATIONAL FILING DATE

15 July 2004

PRIORITY DATE CLAIMED

15 July 2003

TITLE OF INVENTION

MULTIPARTICLE PHARMACEUTICAL DOSAGE FORM CONTAINING A MUCOADHESIVELY FORMULATED PEPTIDE OR PROTEIN ACTIVE SUBSTANCES METHOD FOR PRODUCING SAID PHARMACEUTICAL DOSAGE FORM

APPLICANT(S) FOR DO/EO/US

Rosario LIZIO, et al.

MAIL STOP PCT

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☐ Express Mail Label No.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 107564096	INTERNATIONAL APPLICATION NO. PCT/EP04/07882	ATTORNEY'S DOCKET NUMBER 282276US0PCT												
23. Other items or information: Application Data Sheet/Notice of Priority/PCT/IB/304/PCT/IB/308/ PTO-1449/Cited References (13)/Statement of Relevancy														
The following fees have been submitted:		CALCULATIONS PTO USE												
24. <input checked="" type="checkbox"/> Basic national fee \$300	\$ 300.00													
25. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ... \$0 All other situations. \$200	\$ 200.00													
26. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. \$400 All other situations. \$500	\$ 400.00													
TOTAL OF 24, 25 and 26 =		\$ 900.00												
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.														
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 15%;">Total Sheets</th> <th style="width: 15%;">Extra Sheets</th> <th style="width: 35%;">Number of each additional 50 or fraction thereof (round up to a whole)</th> <th style="width: 35%;">RATE</th> </tr> <tr> <td style="text-align: center;">- 100 =</td> <td style="text-align: center;">0 /50 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$250.00</td> </tr> </table>	Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE	- 100 =	0 /50 =	0	x \$250.00	\$ 0.00					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE											
- 100 =	0 /50 =	0	x \$250.00											
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$ 130.00												
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 15%;">CLAIMS</th> <th style="width: 15%;">NUMBER FILED</th> <th style="width: 35%;">NUMBER EXTRA</th> <th style="width: 35%;">RATE</th> </tr> <tr> <td>Total claims</td> <td style="text-align: center;">32 - 20 =</td> <td style="text-align: center;">12</td> <td style="text-align: center;">x \$50.00</td> </tr> <tr> <td>Independent claims</td> <td style="text-align: center;">1 - 3 =</td> <td style="text-align: center;">0</td> <td style="text-align: center;">x \$200.00</td> </tr> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	32 - 20 =	12	x \$50.00	Independent claims	1 - 3 =	0	x \$200.00	\$ 0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE											
Total claims	32 - 20 =	12	x \$50.00											
Independent claims	1 - 3 =	0	x \$200.00											
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00		\$ 0.00												
TOTAL OF ABOVE CALCULATIONS =		\$ 1,630.00												
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.														
SUBTOTAL =		\$ 1,630.00												
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$ 0.00												
TOTAL NATIONAL FEE =		\$ 1,630.00												
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +		\$ 0.00												
TOTAL FEES ENCLOSED =		\$ 1,630.00												
Amount to be		\$												
Amount to be		\$												

10/564096

PTO-2038 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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- AP20 RES'PT PTO 11 JAN 2006
- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer Number
22850

Surinder Sachar
SIGNATURE

Norman F. Oblon

NAME

24,618

REGISTRATION NUMBER

Jan 11 2006
DATE

Surinder Sachar
Registration No. 34,423